

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

VICTOR PADUANO, FRANK SCALA,)	
NICK CANNER on behalf of themselves and)	
other similarly situated Individuals, and HM)	
COMPOUNDING SERVICES, LLC,)	
)	
Plaintiffs,)	
)	
vs.)	Case No.
)	
EXPRESS SCRIPTS, INC., CVS)	
CAREMARK CORP., OPTUMRx, INC., and)	
PRIME THERAPEUTICS LLC,)	
)	
Defendants.)	
_____)	

NOTICE OF REMOVAL

PLEASE TAKE NOTICE that Defendants CVS Caremark Corp., now known as CVS Health Corporation (“CVS”), Express Scripts Inc. (“ESI”), Optum Rx (“ORx”) and Prime Therapeutics, LLC (“Prime”) (collectively, “Defendants”), by and through their attorneys, hereby remove this action from the Supreme Court of the State of New York, County of Nassau, to the United States District Court for the Eastern District of New York, pursuant to 28 U.S.C. §§ 1331, 1332, 1441, 1446 and 1453. As grounds for the removal, Defendants state as follows:

Background

1. On September 10, 2014, plaintiffs Victor Paduano, Frank Scala, Nick Canner and HM Compounding Services, LLC (“HMC”) (collectively “Plaintiffs”) filed a complaint (the “Complaint”) captioned as *Victor Paduano, et al. v. Express Scripts, Inc., et al.*, in the Supreme Court of the State of New York, County of Nassau (Index No. 604739-2014),

against Defendants. Service of the summons and Complaint was made on all Defendants on September 11, 2014. *See Exhibit 1.*

2. The Complaint asserts claims for fraud and misrepresentation (Count I); violation of Section 349 of the New York General Business Law (Count II); violation of Section 340 of the New York General Business Law (Count III); unfair insurance practices based on alleged violations of state statutes, including but not limited to, New York Insurance Law Sec. § 2401, *et seq.* (Count IV); and seeks a permanent injunction remedy (Count V).

3. Removal of this action is proper because this is a civil action that falls under the Court's original jurisdiction for three independent reasons. First, complete diversity exists between the parties, and the amount in controversy exceeds \$75,000, exclusive of interest and costs. *See* 28 U.S.C. §§ 1332(a), 1441(b). Second, Plaintiffs have filed a complaint "on behalf of themselves and other similarly situated individuals" and removal is authorized by the Class Action Fairness Act of 2005, Pub. L. No. 109-2, as codified at 28 U.S.C. §§ 1332(d) and 1453 ("CAFA"). Third, Plaintiffs have asserted claims arising under federal law. *See* 28 U.S.C. §§ 1331, 1441(a).

4. All Defendants join in this removal.

5. This removal is timely under 28 U.S.C. § 1446(b) in that it has been filed within thirty days of first service of the summons and complaint. *See Murphy Bros. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 350 (1999) (holding that the thirty (30) day removal period does not begin to run until a defendant is formally served with summons and the petition).

6. Pursuant to the requirements of 28 U.S.C. §1446(d), Defendants will promptly notify Plaintiffs in writing of the filing of this Notice of Removal. *See Exhibit 2.*

7. Pursuant to the requirements of 28 U.S.C. §1446(d), Defendants will also promptly advise the Clerk of the Supreme Court of the State of New York, Nassau County, of the removal of the State Court Action by filing a Notice of Filing of Notice of Removal (which will include a copy of this Notice of Removal) with the Clerk. *See* **Exhibit 2**.

8. Pursuant to the requirements of 28 U.S.C. §1446(a), this Notice of Removal is filed in the District Court of the United States for the District and Division in which the case is pending.

9. Pursuant to 28 U.S.C. § 1446(a), a true and correct copy of the summons and the Complaint is attached hereto as **Exhibit 1**. No other pleadings have been filed in the state court action.¹

Complete Diversity Exists Between the Parties

10. Plaintiffs have alleged that Plaintiff HMC is, and was at the time of filing the Complaint, a resident of New York; Plaintiff Paduano is, and was at the time of filing the Complaint, a resident of New York; Plaintiff Scala is, and was at the time of filing the Complaint, a resident of New York; and Plaintiff Canner is, and was at the time of filing the Complaint, a resident of New York. (Compl. ¶¶ 4-7.) Upon information and belief, none of the members of HMC reside in any state in which any defendant is a citizen.

11. At the time this action was commenced and at all times since, Defendant CVS has been a corporation organized and existing under the laws of Delaware, with its

¹ Plaintiffs have filed a motion before the Supreme Court of the State of New York, Nassau County, seeking a temporary restraining order, which was granted.

principal place of business in Rhode Island. Therefore, for purposes of 28 U.S.C. § 1332 and 28 U.S.C. § 1441, CVS is a citizen of the States of Delaware and Rhode Island.²

12. At the time this action was commenced and at all times since, Defendant Express Scripts has been a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Missouri. Therefore, for purposes of 28 U.S.C. § 1332 and 28 U.S.C. § 1441, Express Scripts is a citizen of the States of Delaware and Missouri.

13. At the time this action was commenced and at all times since, Defendant ORx has been a corporation organized and existing under the laws of the State of California, with its principal place of business in California. Therefore, for purposes of 28 U.S.C. § 1332 and 28 U.S.C. § 1441, ORx is a citizen of the State of California.

14. At the time this action was commenced and at all times since, Defendant Prime has been a limited liability corporation. The members of Prime and their states of incorporation and principal place of business are as follows:

- Pharmacy Gold, Inc., a Minnesota corporation
 - Principal Address: 3535 Blue Cross Road, Eagan, MN 55121
- Prime Therapeutics, Inc., a Delaware corporation
 - Principal Address: 1305 Corporate Center Drive, Eagan, MN 55121
- Blue Cross and Blue Shield of Wyoming, a Wyoming non-profit corporation

² Defendant CVS Caremark Corporation is improperly named as a defendant. On September 3, 2014, CVS Caremark Corporation was renamed “CVS Health Corporation.” CVS Caremark Corporation was, and CVS Health Corporation is, a parent holding company. For ease of reference, the entity will be referred to herein as “Caremark.” In any event, Caremark does not operate any retail pharmacies or provide pharmacy services as a pharmacy benefits manager. It is merely a parent company. It is well-settled that parent entities are not liable for alleged acts of subsidiaries. *See, e.g., U.S. v. Bestfoods*, 254 U.S. 51, 61 (1998) (“It is a general principle of corporate law deeply ‘ingrained in our economic and legal systems’ that a parent . . . corporation is not liable for the acts of its subsidiaries.”) (internal citation omitted). While reserving its rights, Caremark joins in the removal of this action.

- Principal Address: 4000 House Avenue, Cheyenne, WY 82001
- Noridian Mutual Insurance Company, a North Dakota corporation
 - Principal Address: 4510 13th Avenue SW, Fargo, ND 58121
- Blue Cross and Blue Shield of Kansas, Inc., a Kansas corporation
 - Principal Address: 1133 Topeka Boulevard, Topeka, KS 66629
- Health Care Service Corporation, A Mutual Legal Reserve Company and Illinois Insurance Company
 - Principal Address: 300 East Randolph Street, Chicago, IL 60601
- Blue Cross and Blue Shield of Florida, Inc., a Florida corporation
 - Principal Address: 4800 Deerwood Campus Parkway, Jacksonville, FL 32246
- Blue Cross and Blue Shield of Alabama, Inc., an Alabama non-profit corporation
 - Principal Address: 450 Riverchase Parkway East, Birmingham, AL 35244
- NobleHealth, Inc., a North Carolina corporation
 - Principal Address: 1830 US 15-501 North, Chapel Hill, NC 27514, P.O. Box 2291, Durham, NC 27702

Therefore, for purposes of 28 U.S.C. § 1332 and 28 U.S.C. § 1441, Prime is a citizen of the States of Minnesota, Delaware, Wyoming, North Dakota, Kansas, Illinois, Florida, Alabama, and North Carolina.

15. Upon information and belief, none of the members of Plaintiff HMC are citizens of any state in which any defendant is a citizen for purposes of 28 U.S.C. § 1332 and 28 U.S.C. § 1441. Defendants have made diligent efforts to identify the corporate citizenship of Plaintiff HMC through publicly-available records and otherwise, and as of the date of this filing are aware of no information that would suggest that any member of Plaintiff HMC is a citizen of any state in which any defendant is a citizen. Accordingly, upon information and belief, none of the Plaintiffs are citizens of a state where any of the Defendants have citizenship, and therefore complete diversity exists between the parties.

16. The First Cause of Action of Plaintiffs' Complaint alleges fraud and misrepresentation and seeks monetary damages. (Compl. ¶¶ 77-81 and p. 29.)

17. The Second Cause of Action of Plaintiffs' Complaint alleges violations of Section 349 of the New York General Business Law and seeks treble monetary damages, punitive damages and attorney's fees. (Compl. ¶¶ 82-91 and pp. 29-30.)

18. The Third Cause of Action of Plaintiffs' Complaint alleges violations of Section 340 of the New York General Business Law and seeks treble monetary damages, punitive damages and attorney's fees. (Compl. ¶¶ 92-98 and pp. 30-31.)

19. The Fourth Cause of Action of Plaintiffs' Complaint alleges unfair insurance practices and seeks injunctive relief requiring, among other things, that Defendants reimburse pharmacies for compound medicines. (Compl. ¶¶ 99-103 and pp. 31-32.)

20. The Fifth Cause of Action of Plaintiffs' Complaint seeks a permanent injunction requiring, among other things, that Defendants reimburse pharmacies for compound medicines. (Compl. ¶¶ 104-106 and pp. 32-33.)

21. The amount in controversy exceeds the sum of \$75,000, exclusive of interest and costs, and for the purposes of diversity jurisdiction and removal, this is a controversy between citizens of different States.

22. In sum, because Plaintiffs are seeking monetary relief as well as injunctive relief that itself exceeds \$75,000, the jurisdictional threshold has been met. Taken together, they plainly satisfy the amount in controversy requirement for diversity jurisdiction.

Removal Is Appropriate Under CAFA

23. This Court also has original jurisdiction over this action pursuant to 28 U.S.C. §§ 1332(d) and 1453, the Class Action Fairness Act ("CAFA").

24. The Complaint was filed on behalf of Plaintiffs and “other similarly situated individuals” and seeks injunctive relief that would apply nationwide to all compounding pharmacies. (*See* Compl. Plaintiffs’ Caption; *see also* Compl. ¶¶ 5-7, and pp. 29-33.)

25. CAFA extends federal jurisdiction to all putative class actions in which: (a) there are one hundred (100) or more members in the proposed class; (b) there is minimal diversity, *i.e.*, at least one (1) member of the proposed class is a citizen of a State different from any Defendant; and (c) the aggregated claims of the individual class members exceed the sum or value of \$5,000,000.00. *See* 28 U.S.C. § 1332(d)(2), (5), and (6). This action satisfies all of these requirements.

A. The Proposed Class Consists of Tens of Thousands of Individuals

26. The Plaintiffs specifically allege that “this class consists of tens of thousands of individuals.” (Compl. ¶¶ 5-7.)

27. Accordingly, it is clear that the individually-named Plaintiffs’ proposed class consists of more than one hundred members.

B. There is Minimal Diversity of Citizenship

28. As set for in paragraphs 10 through 15, above, in connection with removal based on diversity jurisdiction, there is minimal diversity between Plaintiffs and Defendants to satisfy the minimal diversity requirement of CAFA.

C. The Aggregated Claims of the Putative Class Members Exceed \$5 Million Dollars

29. CAFA requires aggregation of the individual putative class members’ claims, exclusive of interest and costs, to determine the jurisdictional amount. *See* 28 U.S.C. § 1332(d)(6).

30. While Defendants dispute the validity of Plaintiffs' allegations and claims, for the purposes of determining whether federal jurisdiction exists, it is clear that the aggregate amount in controversy exceeds \$5,000,000.00.

31. For the purposes of determining whether federal jurisdiction exists, without admitting the validity of Plaintiffs' allegations and claims, it is clear that the aggregate amount-in-controversy exceeds \$5 million dollars. The individual plaintiffs allege their claims on their "own behalf and on behalf of all others who are similarly situated." (Compl. ¶¶ 5-7.) The individual plaintiffs allege "tens of thousands of individuals" similarly situated. (*Id.*) Plaintiff Paduano alleges his compounded medications are required to function "on a day-to-day basis." (*Id.* at ¶ 5.) Plaintiff Scala "daily relies on the compounded medications." (*Id.* at ¶ 6.) Plaintiff Canner "tri-weekly relies on the compounded medications." (*Id.* at ¶ 7.) HM Compounding alone submitted claims to just one of the four defendants that totaled more than \$19,000,000.00 for just January 1, 2014 to September 1, 2014. (Declaration of Michael L. Klein, ¶ 4 (attached as **Exhibit 3**)). Based on these facts, and particularly given Plaintiffs' request for treble damages, punitive damages and attorneys' fees, the amount in controversy exceeds \$5 million dollars.

32. The Complaint alleges that Defendants "have engaged in a concerted and coordinated effort" to deprive patients of medication supplied by compounding pharmacies, undertook coercive behavior to discourage physicians from prescribing compounded medications, and imposed illegal restrictions on compounding pharmacies in an anticompetitive effort to restrict pharmacies from providing medication "all in an effort to put the independent pharmacies out of business and corner the market for compounded drugs" in violation of New York law.

33. The Complaint seeks recovery on behalf of Plaintiffs for injunctive relief requiring Defendants to take action across the entire United States with respect to how they administer prescription arrangements of numerous health plans. (Compl. pp. 29-33.) Plaintiffs also seek damages, including treble damages, punitive damages and attorneys' fees for claims of fraud and misrepresentation and alleged violations of Sections 340 and 349 of the New York General Business Law. (Compl. pp. 29-33.)

34. The Court may also consider Plaintiffs' request for treble damages, punitive damages, and attorneys' fees when determining whether a putative class' aggregated damages exceed the jurisdictional minimum required under CAFA. *See, e.g., Fields v. Sony Corp. of America*, 2014 WL 3877431, at *2 (S.D.N.Y. Aug. 4, 2014); *Servedio v. State Farm Ins. Co.*, 814 F. Supp. 2d 214, 217 (E.D.N.Y. 2011).

35. CAFA expressly states that in considering the amount-in-controversy requirement in a class action, the requested relief of the class is to be aggregated to determine if the five million dollar threshold is met. *See* 28 U.S.C. § 1332(d)(6).

36. Thus, based upon Plaintiffs' allegations, the putative class' aggregated damages exceed the \$5 million jurisdictional minimum required under CAFA. Therefore, this is a civil action over which this Court has original jurisdiction pursuant to 28 U.S.C. § 1332, and is one which may be removed to this Court pursuant to the provisions of 28 U.S.C. §§ 1446 and 1453.

Federal Question Jurisdiction Exists In This Case

37. Independent of traditional diversity jurisdiction, and CAFA, this Court also has original, federal question jurisdiction over this action. *See* 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e) ("ERISA"). A defendant may remove an action to federal court under 28

U.S.C. § 1441 if the complaint presents a federal question, such as a federal claim. *See Avco Corp. v. Aero Lodge No. 735*, 390 U.S. 557, 560 (1968).

38. Federal question jurisdiction exists in this case based on complete preemption of Plaintiffs' claims under the Employee Retirement Income Security Act of 1974, ("ERISA"), 29 U.S.C. § 1001 et seq. (§ 1132(a)). This court has original jurisdiction over ERISA actions. 29 U.S.C. § 1132(e). Furthermore, to the extent that any claim in the Complaint is not preempted, it "form[s] part of the same case or controversy." 28 U.S.C. § 1367(a). This Court thus has supplemental jurisdiction over all remaining parties and claims.

39. Included among the individual Plaintiffs' claims are claims for benefits under their respective group health plans that were denied, confirming that the dispute, at least in part, is over whether the claims are payable under the terms of their respective group health plans, i.e., whether the compounded medications were covered benefits under the terms of the plans (i.e., the "right to payment"). Each of the individual Plaintiffs receive health care benefits under an employer-sponsored plan, which are governed by ERISA.

40. Plaintiffs' Complaint includes disguised benefits claims seeking interpretation of what benefits are owed under the individual Plaintiffs' health plans administered by each of the Defendants, or their subsidiaries, which are pharmacy benefit managers ("PBM"). While their claims have different headings, an "artful pleading on the part of the plaintiff to disguise federal claims by cleverly dressing them in the clothing of state-law theories will not succeed in keeping the case in state court." *Franciscan Skemp v. Central States*, 538 F.3d 594, 596 (7th Cir. 2008).

41. Plaintiffs' Complaint further seeks an interpretation of certain "prescription drug benefits" allegedly available to Plaintiffs (Compl. ¶ 89), alleges improper

denial of “prescription drug benefit coverage to which they are entitled” (Compl. ¶ 96), and seeks injunctive relief preventing Defendants from allegedly “eliminating from insurance coverage . . . compounded medications” prescribed to patients “who have prescription drug benefit coverage administered by a defendant pursuant to a health insurance program” (Compl. p. 29), as well as injunctive relief preventing Defendants from allegedly “denying prescription drug benefit coverage” to Plaintiffs (Compl. p. 30, 31, 32).

42. The individual Plaintiffs’ claims are based upon their allegations that their compounded medication is a covered benefit to which they are entitled under their employee benefit plans. Compl. at ¶¶ 5-7, 46. Plaintiffs’ Complaint alleges that the Defendants, who manage claims for benefits asserted by the putative class members under the terms of their respective ERISA group health plans, have established “arbitrary and impossible” barriers to claims for compound drugs under the terms of the individual Plaintiffs’ respective group health plans. (*E.g.*, Compl. ¶ 38, 39). These “unwarranted” procedural barriers were, according to the individual Plaintiffs adopted to “wrongfully avoid paying claims” under the terms of the individual Plaintiffs’ ERISA group health plans. Thus, the individual Plaintiffs are in effect claiming that the Defendants wrongfully denied claims for benefits under the terms of ERISA group health plans through internal procedures that would result in the denial of appropriate claims.

43. Plaintiffs seek injunctive relief that would prohibit Defendants from:

- Eliminating certain medications from Plaintiffs’ “prescription drug benefit coverage administered by a defendant pursuant to a health insurance program,” (Compl. at ¶ 106(a));

- “Refusing to process and pay claims for payment” submitted by HMC for “patients who have prescription drug benefits administered by a defendant,” (Compl. at ¶ 106(b)); and
- “Denying prescription drug benefit coverage” to the individual Plaintiffs and other similarly situation persons “who have prescription drug benefit coverage which is administered by a defendant.” (Compl. at ¶ 106(d).)

44. The injunctive relief the individual Plaintiffs are seeking can be obtained under 29 U.S.C. § 1132(a)(1)(B) and/or § 1132(a)(3).

45. For the reasons expressed above, Plaintiffs seek recovery of benefits under an employee welfare benefit plan as defined in 29 U.S.C. § 1002(1)(a) of ERISA, and, therefore, Plaintiffs’ state law claims must be treated as claims under ERISA § 502(a), and are therefore removable under the complete preemption doctrine and ERISA, 29 U.S.C. §§ 1132(a), (e) and 29 U.S.C. § 1144(a). A common law or state law claim which asserts a claim by a plan member related to an employee benefit plan regulated by ERISA is actually a claim arising under the laws of the United States which is completely preempted and may be removed, even if it purports to raise only state law claims. *See, e.g., Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987); *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 45 (1987); *Beneficial National Bank v. Anderson*, 539 U.S. 1 (2003).

46. Therefore, this Court has original federal question jurisdiction over this action pursuant to 28 U.S.C. § 1331. As an action of a civil nature founded on a claim or right arising under the laws of the United States, this action may be removed to this Court pursuant to 28 U.S.C. § 1441(a).

No Waiver of Defenses

47. In filing this Notice of Removal, Defendants do not waive any defenses that may be available, including, without limitation, jurisdiction, venue, and the right to compel arbitration under 9 U.S.C. § 1, et seq. Nor do the Defendants admit any of the factual allegations in the Complaint; rather, the Defendants expressly reserve the right to contest those allegations at the appropriate time.

Conclusion

48. For all the foregoing reasons, removal is proper and this Court has original jurisdiction over this case.

WHEREFORE, Defendants respectfully request that this action, captioned as *Victor Paduano et al. v. Express Scripts, Inc., et al.*, Index No. 604739-2014 and currently pending in the Supreme Court of the State of New York, County of Nassau, be removed to this Court, and that the Court grant such other and further relief as it deems necessary and appropriate.

Dated: September 12, 2014

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EXHIBIT 1

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NASSAU

-----X
VICTOR PADUANO, FRANK SCALA, NICK CANNER on
behalf of themselves and other similarly situated Individuals,
and HM COMPOUNDING SERVICES, LLC,

Plaintiffs,

-against-

EXPRESS SCRIPTS, INC., CVS CAREMARK CORP.,
OPTUMRx, INC., and PRIME THERAPEUTICS LLC,

Defendants.

Index No.:

Date Purchased: 9/ /2014

SUMMONS

Plaintiffs' designate Nassau
County as the place of trial.

The basis of the venue is the
Residences' of the Plaintiffs'

-----X
TO THE ABOVE NAMED DEFENDANTS:


YOU ARE HEREBY SUMMONED AND REQUIRED TO SERVE upon the undersigned, Jaspan Schlesinger LLP, 300 Garden City Plaza, Garden City, New York 11530, as attorneys for Plaintiffs', an Answer to the annexed Verified Complaint, which is herewith served upon you, within twenty (20) days after service hereof, exclusive of the day of service or within thirty (30) days after the service is complete, if service is made by any method other than personal delivery to you within the State of New York.

In case of your failure to answer the Verified Complaint, judgment will be taken against you by default for the relief demanded therein.

Dated: Garden City, New York
September 10, 2014

JASPAN SCHLESINGER LLP
Attorneys for Plaintiffs'

By:



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Optum Rx, Inc.
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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NASSAU-----X

VICTOR PADUANO, FRANK SCALA, NICK CANNER on
behalf of themselves and other similarly situated Individuals,
and HM COMPOUNDING SERVICES, LLC,

VERIFIED COMPLAINT

Index No.:

Plaintiffs,

-against-

Date Purchased:

EXPRESS SCRIPTS, INC., CVS CAREMARK CORP.,
OPTUMRx, INC., and PRIME THERAPEUTICS LLC,

Defendants.
-----X

PRELIMINARY STATEMENT

1. Defendants, prescription benefit managers ("PBMs"), have engaged in a concerted and coordinated effort to deprive patients of life-enhancing medications supplied by compounding pharmacies, of which plaintiff HM Compounding Services, LLC is one, by providing false and misleading information to patients about their prescribed medications, using threatening and coercive tactics to discourage physicians from prescribing compounded medications needed by their patients, and imposing inconsistent, burdensome and illegal restrictions on compounding pharmacies in an anticompetitive effort to restrict those pharmacies from providing medication lawfully prescribed by physicians for the health and well-being of their patients, all in an effort to put the independent pharmacies out of business and corner the market for compounded drugs in violation of New York law.

2. The result of Defendants' actions, in addition to its negative impact on the continued viability of independent compounding pharmacies, is to adversely affect the health of patients by

depriving them of medications needed to treat their individual and specialized needs.

3. As a result, plaintiffs are entitled to an injunction enjoining Defendants from engaging in such unlawful conduct, as well as an award of monetary damages suffered by Plaintiffs as a result of Defendants' wrongful conduct towards Plaintiffs.

The Parties

4. HM Compounding Services, LLC ("HMC") and its affiliated pharmacies (collectively referred to as "HMC") is an independently owned, closely held, holding company of various compounding pharmacy with a principal location in Brooklyn, New York. HMC operates one of the largest compounding pharmacies in the Eastern United States and New York City's first compounding pharmacy to be accredited by the Pharmacy Compounding Accreditation Board ("PCAB"). HMC provides custom-made medications, i.e., compounded medicines, to numerous patients, including pediatric patients who cannot take pill versions of particular drugs, patients that cannot tolerate one or more ingredients in manufactured drugs, drugs that are no longer manufactured but are still determined to be safe and effective, and compounds for particular types of treatment, including pain management, dermatological specialties, bio identical hormone replacement, sexual dysfunction and enhancement, compounds for autism, compounds for weight management, and compounds for veterinary use.

5. Victor Paduano ("Paduano"), is an individual residing in Massapequa Park in Nassau County, New York, who requires compounded medication tailored to address his individual health needs and who, daily relies on the compounded medications prescribed by his physician and supplied by HMC, without which he would be unable to function on a day-to-day basis. Paduano has been informed that his medication will no longer be covered by his health insurance company. He sues on

his own behalf and on behalf of all others who are similarly situated who require compounded medications to address their health needs and who are being denied insurance coverage of their medication by Defendants. Upon information and belief, this class consists of tens of thousands of individuals.

6. Frank Scala ("Scala"), is an individual residing in Farmingdale in Suffolk County, New York, who requires compounded medication tailored to address his individual health needs and who, daily relies on the compounded medications prescribed by his physician and supplied by HMC, without which he would be unable to function and engage in daily activities. Scala has been informed that his medication will no longer be covered by his health insurance company. He sues on his own behalf and on behalf of all others who are similarly situated who require compounded medications to address their health needs and who are being denied insurance coverage of their medication by Defendants. Upon information and belief, this class consists of tens of thousands of individuals.

7. Nick Canner ("Canner"), is an individual residing in Franklin Square in Nassau County, New York, who requires compounded medication tailored to address his individual health needs and who, tri-weekly relies on the compounded medications prescribed by his physician and supplied by HMC, without which he would be unable to function and engage in daily activities. Canner has been informed that his medication will no longer be covered by his health insurance company. He sues on his own behalf and on behalf of all others who are similarly situated who require compounded medications to address their health needs and who are being denied insurance coverage of their medication by Defendants. Upon information and belief, this class consists of tens of thousands of individuals

8. Defendant, Express Scripts Inc. ("ESI"), a foreign corporation with its principal place of business in St. Louis, Missouri, is a PBM providing integrated pharmacy benefit management services including network pharmacy claims processing, home delivery pharmacy services and specialty pharmacy benefit management, formulary management and medical and drug analysis services to manage drug plans for health plans, among others. Upon information and belief, ESI is the nation's largest PBM filling annually more than 1.4 billion prescriptions.

9. Defendant CVS Caremark Corp. ("CVSC"), is a foreign corporation with its principal place of business in Scottsdale, Arizona. Upon information and belief, CVSC is the nation's second largest PBM providing comprehensive prescription benefit management services for over 2,000 health plans. In addition, it operates a national retail pharmacy network with over 60,000 participating pharmacies as well as numerous specialty pharmacies and mail order pharmacies including specialty mail order pharmacies.

10. Defendant Optum Rx ("ORx"), is a foreign corporation with its principal office located in Eden Prairie, Minnesota. Upon information and belief, ORx is the third largest PBM in the United States providing pharmacy benefit management services for more than 12 million people nationwide whose clients include UnitedHealth Group's growing health plan business.

11. Defendant Prime Therapeutics, LLC ("Prime"), is a foreign limited liability company with its principal place of business in Eagan, Minnesota. It is an independent pharmacy benefit manager owned by 13 not-for-profit Blue Cross and Blue Shield health plans, subsidiaries or affiliates of those plans that processes claims and delivers medicine to more than 25 million members nationwide. Among other things it provides formulary development, has a Specialty Pharmacy and manages a home delivery service for patient medications.

12. In the United States, PBMs manage 95% of all prescription drugs covered by insurance. ESI, CVSC, ORx and Prime (collectively, “Defendants”) dominate the PBM-market in the United States with a market share of more than 80%.

Background

13. PBMs administer the prescription pharmaceutical portion of healthcare benefit programs, which are typically purchased by a plan sponsor. As part of their functions, PBMs provide bundled services related to the administration of pharmaceutical benefits, including claims adjudication, formulary design, management and negotiation of branded drug rebates, management and negotiation of networks of retail pharmacies, review of drug utilization, processing claims from pharmacies for payment, and the operation of specialty and home-delivery pharmacies such as mail-order pharmacies used to dispense medications directly to patients. Some chain pharmacies, such as CVS have merged with PBMs. Since their inception, PBMs have become multi-billion dollar businesses.

14. Drug compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Plaintiff, HMC is a compounding pharmacy providing patients with medications tailored to their specific needs pursuant to and in accordance with the instructions provided by the patient’s physician.

15. Compounding is an integral part of pharmacy, the science and technique of preparing and dispensing drugs and medicines, and has historically been recognized as a legal and vitally important core component of traditional pharmacy practice.

16. Millions of patients have unique health needs that over-the-counter drugs (“OTCs”) and FDA-approved prescription medications cannot meet. For these patients personalized medication solutions prescribed by licensed physicians and prepared by trained and licensed pharmacists are the only way to achieve the health benefits required by the patient.

17. Unlike commercially available drugs, which are manufactured on a large-scale basis and are not alterable or specifically appropriate for a patient, compounding allows the medication to be tailored to the needs of the patient who for whatever reason cannot or should not take the mass produced drug.

18. For example, if a patient is allergic to a particular ingredient in a commercially available product, the medication can be compounded without the ingredient. If a patient is unable to swallow a commercially available pill, a liquid form can be compounded. If a dosage is too strong for an infant, a lower dosage can be compounded. Flavors can be added to make the medicine more palatable for a child so that the child will take the medicine. Additives for topical creams can be used to prevent skin irritation. Nonessential ingredients such as gluten or dye can be eliminated. Topical creams enable a physician to treat a patient's pain at the site of the pain often avoiding the need for oral or injected narcotic drugs which can result in dependency.

19. In recent years, compound drugs have been prescribed in response to the Food and Drug Administration's 2012 mandate to seek alternatives to addictive opioid narcotics. Compounded medicines are a critical tool for physicians to accomplish this objective because they can allow patients to reduce or avoid the use of oral narcotics that affect the entire body and can lead to opioid abuse.

20. Both the Food and Drug Administration (“FDA”) and New York State regulate the

practice of drug compounding by pharmacists who compound medicines in the State of New York.

~~21. Without access to the compounded medications those patients who require~~
medications tailored to meet their individualized needs are denied the treatment needed to address their health situation.

Defendants' Efforts to Eliminate Competition and Deny Patients the Medicine they Need.

22. Defendants have engaged in a concerted and coordinated effort to eliminate plaintiff HMC, and other independent compounding pharmacies, as competitors in the prescription benefit drug market by placing unwarranted and illegal restrictions on the delivery of compounded medications to patients.

23. Defendants have used their collective market power to launch a concerted attack on the compound medicine industry in an effort to end all coverage for compound medicines and to put independent compounding pharmacies out of business. Upon information and belief, Defendants joined together in approximately 2013 to study compound medicine prescribing trends and to collectively determine how to best eradicate coverage for compounded medicines in 2014.

24. Upon information and belief, after surreptitiously gathering information about physician prescribing trends and compound pharmacy dispensing practices, Defendants joined together to intimidate physicians who prescribed compounded medicines and the patients who take them; to effectuate insurmountable obstacles for pharmacies to receive reimbursement for compounded medicines; to eliminate coverage for all compounded medicine by denying coverage for the ingredients used to prepare them, and to put independent compounding pharmacies out of business.

Coercing Physicians and Materially Misleading Patients

25. Defendants initiated their plan to illegally deny patients coverage for compounded drugs through a series of concerted steps. First, upon information and belief, in approximately 2013, Defendants began targeting independent compounding pharmacies through extensive and rigorous auditing processes. These audits were used to identify network providers that prescribe compounded medicines and the network providers that prepare them. Upon information and belief, Defendants used the data collected through these clandestine audits to identify the doctors that prescribe compounded medicines and to target, intimidate, and coerce them to stop writing those prescriptions immediately or face accusations of fraud and abuse and/or termination of their provider agreements--despite the fact that compound medicines were covered under those agreements. Upon information and belief, those physicians were instructed to cease writing prescriptions regardless of the individual patient's needs and regardless of the prescribing physician's assessment of the treatment most effective for the individual patient.

26. Upon information and belief, Defendants then began contacting patients directly by letter to inform them that their compound medicines would no longer be covered by their prescription benefit policies. To justify this position, Defendants provided misleading statements about the patients' compound drug medicines.

27. For example, ESI sent letters to patients containing the following statements:

To help safeguard your health and protect you from taking medications that not approved by the Federal Drug Administration (FDA), we periodically review your prescription drug claims history. . . . Compounded drugs may contain ingredients that are not FDA-approved for a specific condition and can be subject to quality and potency issues that can be a safety concern. Such compounded drug products are unproven, and are generally for experimental or investigational use . . . [Y]ou will need to replace your compounded prescription with a prescription for an FDA-approved product. This will protect your health . . . Please ask your doctor to prescribe an oral or topical FDA-approved product as an alternative to the

compounded prescription.

28. And ORx sent patients letters with the following statements:

Effective July 1, 2014, your compound medication prepared by your pharmacy is no longer covered under your pharmacy benefit plan because it contains a bulk chemical or ingredient that has not been approved by the U.S. Food and Drug Administration (FDA). Prescription Drug Products covered under your pharmacy benefit plan must be approved by the FDA. FDA-approved medications are available to treat conditions for which some doctors prescribe compound medications.
(Emphasis in original.)

29. Upon information and belief, each of the Defendants sent letters and/or had similar communications with patients. The statements contained in these letters, however, are materially misleading and deceptive.

30. Under the Drug Quality and Security Act ("DQSA"), which was signed on November 27, 2013, certain sections of the Federal Food, Drug, and Cosmetic Act ("FDCA") were modified. Under the revised section 503A of the FDCA, compounding facilities are specifically *exempted* from sections of the FDCA relating to (1) compliance with current good manufacturing practices ("CGMP") (section 502(f)(1), and (2) labeling with adequate directions for use (section 502(f)(1), and (3) FDA approval prior to marketing (section 505).

31. Despite these exemptions, Defendants have concerted to mislead patients and the public at large about how these federal regulations apply to compound medicine. Defendants have intentionally sent misleading letters in an effort to scare and dissuade patients from taking any compound medicines. Defendants misleading propaganda is intended to confuse the public and to steer them away from the treatment prescribed by their doctors.

32. Upon information and belief, each of the Defendants has represented to patients that

compound drugs are "experimental" and therefor unsafe because they are not "FDA approved". However, Defendants failed to advise those patients that all so-called "off-label" use are "experimental" and that PBMs continue to cover mass-produced off-label drugs, even though they are not proven safe and effective for an off-label purpose, because it is a generally accepted principal that off-label or "experimental" drug use is appropriate when prescribed by a licensed physician. Further, PBMs have suggested to patients that they are protecting patients' interests by rejecting all claims for drugs not approved for market by the FDA. But Defendants have omitted from these communications the fact that compound medicine is specifically exempted from that requirement under federal law because lawmakers recognize the important role compound medicine plays in treating patients.

33. Defendants' have further misled patients by asserting that the drugs are not safe because they have not gone through the FDA approval process. This statement, while technically accurate, is misleading because it omits the material fact that under federal law, compound drugs are exempt from the FDA approval process. This is because lawmakers have explicitly recognized that compound medicine can be safe and effective when properly prescribed and prepared, even though the drugs were not subject to the FDA approval process.

34. Defendants also failed to inform patients of the federal and state oversight measure that govern compound pharmacists to oversee the proper compounding of compound medicines.

35. Under New York law, "[t]he practice of the profession of pharmacy is defined as the administering, preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority. . .[.]" (N.Y. Educ. Law § 6801 (emphasis added)). A pharmacy in the State of New York is defined to mean "any place in

which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.” (N.Y. Educ. Law § 6802(1) (emphasis added).) The practice of the profession of pharmacy, including compounding, is therefore specifically contemplated and regulated under the Education Law.

36. Further, the New York State Board of Pharmacy sets the standards that apply to drug compounding in the State of New York. .” (N.Y. Educ Law § 6804.) Accordingly, federal regulation and state statutes and guidelines work in tandem to regulate how pharmacists prepare compounded drugs in the State of New York (and the other states in the union). Under this framework, the FDA does not and cannot approve compounded medications because each medication is different and specifically designed to address each patient’s individualized health requirements and needs. However all of the compound drug ingredients used by HMC are legal and deemed medically necessary by the prescribing physician.

37. By omitting this material information about compound drugs, Defendants intended to scare patients and steer them away from the compound medicines prescribed by their doctors. Upon information and belief, Defendants anticipated that these tactics would also sway patients from objecting to this offensive change in coverage for prescription drug benefits. Defendants’ letters to patients were materially misleading and deceptive.

Attacking the Compound Pharmacies

38. Upon information and belief, after gathering and reviewing the prescribing data,

Defendants quietly instituted a policy of requiring prior authorizations for compounded medicines that exceeded a threshold dollar amount that was intentionally set by Defendants to be an amount too low to cover most, if not all, compounded medicine claims. Upon information and belief, Defendants continued to rigorously monitor and adjust that threshold amount to ensure that compounded medicine claims would categorically be denied coverage without any formal changes to the prescription drug plans being managed by Defendants. Defendants collectively took these actions as part of a concerted effort to change patients' prescription drug benefit coverage without being held accountable to patients, physicians, or pharmacies, and in violation of the laws intended to protect prescription benefit policy holders and all consumers in the State of New York.

39. Upon information and belief, as part of their plan to eliminate compound drugs, Defendants then began manufacturing unwarranted reasons to terminate and/or suspend compound pharmacies' contracts in order to wrongfully avoid paying claims for compounded medicines that were being prescribed after Defendants' warnings to physicians to stop prescribing them even though those medicines were covered under the prescription benefit policies being managed by Defendants.

40. Upon information and belief, by collectively "auditing" independent compounding pharmacies, Defendants were able to terminate and/or suspend Provider Agreements with independent compounding pharmacies, including HMC, without providing notice to those pharmacies of any purported violations of the agreements and without being held accountable to the patients whose prescriptions were being affected by Defendants' plan to eliminate coverage for compounded drugs. As a result of Defendants' illegal conduct, HMC has not been reimbursed for thousands of prescriptions filled pursuant to physician's scripts, causing HMC to suffer economic damages in an amount to be determined.

Defendants' Concerted Attack to Eliminate Coverage Under the Policies

41. Upon information and belief, at or about the same time, Defendants each announced a formal plan to effectively eliminate coverage for compounded medicines managed by each of the defendant PBMs.

42. On May 30, 2014, CVSC announced a new policy in their provider manual related to copayment collection and claims for compounds. This co-payment collection policy marked a drastic change from CVSC's prior policy and required onerous steps intended to result in the rejection of all claims for compounded medicine.

43. Further, effective May, 30 2014, CVSC announced that compounders must include not only the NDC number of each ingredient used in the compound, but also "at least (2) scientifically valid studies in peer-reviewed journals supporting the clinical efficacy of the additional ingredients" for each ingredient and make those available for CVSC review upon request. CVSC knows this requirement is impossible to meet because of the lack of peer reviewed medical literature on compounded preparation and their individual ingredients at this time.

44. By implementing these policies, defendant CVSC has created administrative hurdles designed to deny coverage effective immediately for legitimate prescriptions and to prevent patients from getting the medications they need. Moreover, these hurdles have been applied only to drug compounds, not other products being used for off-label purposes.

45. Similarly, on or about June 3, 2014, ESI launched its new "Compound Management Solution" program and launched a formal campaign to inform providers that it would not pay for claims for compounded medicines. Upon information and belief ESI, forced the plan upon all clients

to become effective either on July 15, 2014 or September 15, 2014, depending on the client's administrative response to the announcement.

46. Upon information and belief, the "solution" will eliminate the prior authorization option for compounded drugs and instead will "automatically reject" any claim for a compounded medicine. Further, effective September 15, 2014, ESI will no longer provide coverage for 1,000 compound drug ingredients that will be identified on a "list" that has yet to be provided by the company. Thus, ESI has essentially announced that effective September 15, 2014, it is cutting off its almost 40% market-share of prescription drug benefit reimbursement for *all* compounded drugs except intravenous medicines.

47. Upon information and belief, without coverage of these chemicals and other bulk compound ingredients, HMC will not be able to fill the overwhelming majority of prescriptions prescribed by physicians for their patients.

48. Defendant ORx has launched a similar attack. Upon information and belief, representatives from ORx have admitted to targeting the top 100 prescribers of compounded medications for "discussions" about their prescribing practices, have begun excluding coverage for bulk compound ingredients, and have instituted policies to require and deny authorizations for any compounded prescriptions.

49. ORx (and other large PBMs) has also imposed impossible pharmacy network requirements to remain a future network provider of compounded medicines. For example, ORx has informed HMC (and presumably all other independent compounding pharmacies) that URAC accreditation is now required to provide network compounding services. However, when HMC contacted URAC to begin the accreditation process, HMC was told that there is no URAC

certification program available for independent pharmacies that solely provide compound medicine services. This is yet another way the giant PBMs are coyly removing all independent compounding pharmacies from the market they control.

50. Through these concerted actions, Defendants intended to use their market power to effectively eradicate the prescription drug benefit buyers' market for compound drugs, which is effectively eliminating the market for compound drugs, and to put all independent compounding pharmacies out of business.

Defendants' Attacks on HMC

ORx

51. By Termination Letter dated March 3, 2014, ORx informed Third Party Station ("TPS"), a Third Party Administrator in ORx's prescription benefit program, that HMC was being terminated as a network provider because the Pharmacy Network Agreement "prohibits delivering, shipping, mailing and/or dispensing Covered Prescription Services to members" and demanded that HMC cease and desist from engaging in such activity.

52. By letter dated March 17, 2014, attorneys for HMC responded to that Termination Letter, explaining that the contract provision cited by ORx did not prohibit "delivering, shipping" and/or "dispensing" prescription services to members, nor could it if it were to comply with governing legal and ethical requirements for these services under New York law. By letter dated May 29, 2014, ORx responded to that letter asserting that HMC's contract was being terminated immediately "for cause" on the basis that the "Pharmacy understood that mailing, shipping and/or delivering of Covered Prescription Services is not allowed under the retail contract with ORx. . .".

53. Dispensing medication by mail is a permitted practice under New York law and

regulations and the restriction imposed by ORx contravenes public policy because it deprives insured patients with access to the pharmacy of their choice to obtain the compounded medications required for their health needs.

54. Subsequently, by letters dated June 25, 2014, ORx informed HMC that it was terminating “for cause” HMC’s New Jersey and New York compounding pharmacies’ Pharmacy Network Agreement with Wholesale Alliance TPS, LCC d/b/a Third Party Station for alleged “Fraud, Waste and Abuse” for purportedly engaging in “prescription splitting to obtain multiple dispensing fees, etc.” By letter dated July 16, 2014, HMC explained that it was not “splitting” prescriptions and receiving multiple dispensing fees and requested that the contract be reinstated until an appeal hearing on the issue was held. ORx denied that request, causing HMC significant money damages.

CVSC

55. By letter dated June 30, 2014, CVSC informed HMC of its “ongoing audit” of its pharmacy “covering the period of April 2013 through September 30, 2013.” That “ongoing audit” had not been previously disclosed to HMC. In that letter, CVSC informed HMC that “CVS Caremark is placing your pharmacy under payment and adjudication suspension” effective immediately based upon purported “compliance issues” identified in the ongoing audit. CVSC informed HMC that pursuant to this decision, HMC “may not submit claims to CVS Caremark for adjudication” and that “future cycle checks for prior claims will be withheld pending resolution of our audit review.” Accordingly, effective June 30, 2014, CVSC stopped paying claims submitted by HMC and precluded HMC from submitting any future claims.

56. By letter dated July 16, 2014, HMC sent a letter to CVSC addressing its stated audit

concerns and requested that CVSC reinstate HMC. By letter dated July 28, 2014, CVSC denied HMC's request to reconsider the payment and adjudication suspense placed upon HMC. In that letter, CVSC admitted that it had begun a policy of rejecting compounded prescriptions and requiring prior authorizations "based upon plan edits." No information about the "plan edits" was provided in that letter, nor were those "plan edits" disclosed to HMC prior to the termination letter. CVSC went on to state: "We do not believe that there is any patient harm with our decision to suspend payment and claims adjudication for HM Compounding...". CVSC provided no support for this conclusion.

ESI

57. By letter dated July 22, 2014, HMC informed ESI that it had become aware that ESI was directly notifying providers that they were not to continue prescribing compounded medications even if it was in the patient's best interest to receive compounded medicine. In retaliation for HMC's complaint, ESI, just seven days later, on July 31, 2014, sent HMC a "notice of immediate termination" of HMC's Provider Agreement with ESI. In its letter, ESI alleged that HMC had purportedly made material misrepresentations to ESI regarding collecting patients' co-payments and

as a result was terminating HMC's contract immediately. Then, one day later, by letter dated August 1, 2014, ESI responded to HMC's July 22, 2014 letter. In that letter, ESI did not deny making such statements to prescribing physicians; rather, it took the position that ESI "has a legal right to communicate with providers regarding benefit coverage issues."

Defendants' Deceptive and Unfair Trade Practices

58. In furtherance of this scheme, Defendants have also engaged in unfair and outrageous tactics designed to cause HMC to violate Defendants' policies in order to manufacture a reason to terminate their relationship and deny it the right to be reimbursed for prescriptions it fills for their

insureds.

Purported "Split Fills"

59. For example, Defendants CVSC and ORx and have accused HMC of "split filling" prescriptions in violation of their rules. Split filling is a term that describes a pharmacy "splitting" one prescription in order to impermissibly collect multiple dispensing fees from the same prescription. Splitting the prescription to increase pharmacy fees is not permitted under the provider agreements. However, HMC has never engaged in splitting prescriptions to increase dispensing fees, nor has HMC accepted from any patient multiple dispensing fees for a single compound prescription.

60. At or about the time Defendants implemented their plan to reject all compound medicine claims, the claims being processed by HMC began to be rejected when the prescription issued by a patient's doctor exceeded the PBM's cost allowance for the medication. In such instances, it was HMC's custom and practice to contact Defendants' help desk to determine if it was permissible to partially fill the prescription so that the patient could receive the medicine prescribed by the treating physician. Defendants' representatives authorized HMC to partially fill its prescriptions and relying on that advice, HMC partially filled numerous prescriptions without accepting any additional dispensing fees in order to process the prescription claims.

61. HMC received no additional money for the partial fills and, in fact, lost money on each prescription because the pharmacist had to dispense future fills without charging a dispensing fee.

62. Despite advising HMC that it could partially fill prescriptions to process the claims, Defendants subsequently asserted that by doing so HMC had improperly engaged in split filling for which Defendants terminated HMC's provider agreement.

63. By deceptively advising HMC that it is permissible to partially fill a prescription to meet the cost caps imposed by Defendants only to use the fact that HMC relied on that advice as a basis for terminating HMC's contract so that it can no longer be reimbursed for any of the prescriptions that it fills, Defendants have engaged in deceptive and unfair business practices.

64. As explained, Defendants have collectively and in concert acted together to impose impossible restrictions on independent compound pharmacies that process claims for compounded drugs. These barriers will effectively eliminate independent compound pharmacists from filling prescriptions for compounded drugs.

No Mail Fulfillment Requirements

65. Upon information and belief, Defendants' motive in implementing the "no mail fulfillment" restriction and its application to other non-mail methods of delivery is to eliminate competition from HMC and other independent compounding pharmacies, by requiring the insureds who wish to receive their compound prescriptions by mail to obtain them only from the Defendants' prescriptions by mail program.

66. Similarly, ORx's (and upon information and belief other PBMs) insurmountable obstacle that independent compounding pharmacies be URAC certified is another thinly-veiled ploy to eliminate independent compounding pharmacies from the market. URAC, an independent non-profit accrediting organization, only certifies pharmacies that dispense FDA approved manufactured medications. It does not have an accreditation program for compounding pharmacies which only make compounded medications tailored to the specific needs of the patient.

67. Upon information and belief, ORx is requiring this certification because it maintains a specialty pharmacy that qualifies for URAC certification under the umbrella of ORx's other retail

pharmacy services. In other words, while all independent compound pharmacies will be precluded from dispensing and delivering compounded medicines, ORx (and the other PBMS) will continue to be able to deliver compound medications to patients by mail or other delivery services which are the same as those which would be used by HMC.

68. Upon information and belief, there is no legitimate reason why HMC and other compounding pharmacies should be restricted from using the United States mail or other delivery services to deliver medicines to patients in the same manner utilized by defendants. Upon information and belief, the reason defendants have imposed the prohibition is to limit competition by requiring patients who want or need to have their medications delivered to them only obtain them from Defendants.

FDA-Approved and Peer Review Article Requirements

69. Defendants' requirement that compound drugs be FDA-approved and supported by peer-reviewed articles are requirements that are equally impossible to meet. Because compound medicines are exempted from the FDA-approval process (which typically requires an investment of several billion dollars, in part, to fund the studies that generate the peer-reviewed literature), these requirements are simply an arbitrary and impossible barrier to coverage erected by Defendants to eliminate compound drugs from the prescription benefit drug market.

The Effect of Defendants' Anticompetitive Actions

70. PBMs manage 95% of all prescription drugs covered by insurance and Defendants control virtually the entire PBM market. Without the ability to submit claims for payment for the prescriptions that it fills for Defendants' members, HMC and other independent compounding pharmacies will be forced out of business, which upon information and belief, is the goal of the

Defendants.

71. Upon information and belief, based on the timing of the actions described, Defendants coordinated their efforts in an attempt to eliminate competition by HMC and other compounding pharmacies.

72. The effect of the Defendants' action is not only to drive HMC and other compounding pharmacies out of business but to deprive patients of the life-enhancing medications that they need to address their medical conditions and which have been prescribed for them by their doctors.

73. Defendants can do this because they control the market that purchases prescription drugs through employer-sponsored health insurance programs. By joining together to use their market power to control the drugs that physicians prescribe and to coerce physicians to prescribe less effective, mass-produced drugs to patients who are better served by specialty drugs, Defendants are driving out compound drugs as a market sub-class in the prescription drug benefit market.

74. Defendants have engaged in this behavior to eliminate compound drugs from the prescription drug benefit market so that Defendants' preferred mass produced drugs will be prescribed and purchased, thereby eliminating the sub-class of compounded medicines at the expense of the prescription drug market as a whole.

75. Defendants' effort to switch a patient from a compounded medication to a mass-produced drug is solely cost-driven by the PBMs and disregards the patients' medical and health requirements as determined by their physicians. In other words, defendants are driving patients to less costly and less effective medications which are not in the patients' best interest as determined by their doctor.

76. Defendants' actions are intentionally designed to both eliminate HMC and other

compounding pharmacies as competitors and to force patients to accept less effective medication for their medical problems simply so that defendants can make more money.

**AS AND FOR A FIRST CAUSE OF ACTION
(FRAUD AND MISREPRESENTATION)**

77. Plaintiffs repeat and reallege each and every allegation made in the preceding paragraphs of this Complaint, as though more fully set forth at length herein.

78. In the letters sent to patients advising them to stop taking compound drugs, Defendants made material misrepresentations that concealed or suppressed material facts from the class of Plaintiff patients about the safety, efficacy, and government regulation of compound medicines. Such misrepresentations and suppressed material facts include but are not limited to those listed in paragraphs 22-37 and 58-64. Specifically, Defendants failed to tell patients that compound drugs are exempted from the FDA-approval process, are subject to safety oversight regulation by both the federal and New York State governments, and are considered by the treating physician to be a safe and effective drug for that patient's medical condition. Defendants further failed to inform patients that their decision to eliminate an entire type of medical treatment under their insurance policies is against the law.

79. The omissions and misrepresentations by Defendants were material and were false and misleading, and Defendants knew they were false and misleading at the time they were made, or, at a minimum, acted with reckless disregard for the truth or falsity of the representations made about the safety and efficacy of compound drugs and legality of their actions in attempting to end patients' prescription drug coverage for compound drugs.

80. Defendants misrepresented, concealed, or suppressed these facts with the intent to influence the actions of the Plaintiff class to steer patients away from using compound drugs, and to

prevent patients from objecting to the prescription benefit changes being effectuated by Defendants.

81. The members of the Plaintiff patient class reasonably and justifiably relied on Defendants' misrepresentations in believing that Defendants had the right to terminate coverage for compound medicines and by either taking less medically appropriate mass produced drugs and/or paying for compound medicines.

**AS AND FOR A SECOND CAUSE OF ACTION
(DECEPTIVE TRADE PRACTICES: VIOLATION OF
SECTION 349 OF THE NEW YORK GENERAL BUSINESS LAW)**

82. Plaintiffs repeat and reallege each and every allegation made in the preceding paragraphs of this Complaint, as though more fully set forth at length herein.

83. New York General Business Law ("GBL") § 349 prohibits any business or person from engaging in deceptive business practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York state.

84. As alleged herein, through written and oral communications, Defendants have engaged in material deceptive or misleading consumer-related business practices that affected consumers, including purchasers and prescribers of compounded medications, a group that includes Plaintiffs, in violation of GBL § 349. Defendants' deceptive or misleading business practices alleged herein are likely to mislead, and have misled, prescribing physicians, reasonable purchasers of compounded medicines, and independent compound pharmacies.

85. These representations and/or omissions of fact were misleading in a material way because they were likely to mislead reasonable physicians to believe that they must stop prescribing medically necessary compounded drugs or be subjected to allegations of fraudulent and abusive prescribing practices, when those practices are recognized under federal and state law as essential

pharmacy functions and medically necessary treatment as determined by the prescribing physicians, not acts of fraud and abuse. Defendant used these tactics to deprive the class of Plaintiff patients from access to medically appropriate and necessary compound drugs.

86. These representations and/or omissions of fact were also likely to mislead the class of Plaintiff patients into believing that compounded medicines are not recognized as medically necessary or appropriate treatments under federal and state law, when, in fact, they are. These representations and/or omissions were also likely to cause HMC and did cause HMC to rely on Defendants' advice about filling prescriptions when Defendants intended to terminate HMC's contracts for following that advice.

87. Defendants deliberately made these material representations while omitting key facts about compounded medicines to steer physicians and patients from using compounded medicines, even when those medicines are deemed by prescribing physicians to be medically necessary under the circumstances and to prevent HMC from dispensing compound medicines, which has negatively impacted all consumers of prescription drugs covered by Defendants in the State of New York.

88. Defendants also made material misrepresentations to HMC about the permissibility of partially filling prescriptions only to improperly accuse HMC of "split filling" prescriptions to increase dispensing costs. In fact, HMC was told by Defendants that it could partially fill prescriptions and HMC never charged a dispensing fee for the future-filled prescription. Nonetheless, Defendants terminated HMC's provider agreement based upon this deceptive claim, causing severe economic injury to HMC.

89. Defendants' violation of GBL § 349 has caused the class of Plaintiff patients to suffer injury including, *inter alia*, being denied access to critical prescription drug benefits; paying for

prescription drugs that should have been covered under the Plaintiff Patients' medical insurance policies; pain and suffering caused by Plaintiff Patients' restricted access to medically necessary prescription drug treatment.

90. Defendants' willfully and knowingly engaged in the conduct alleged herein.

91. Defendants' conduct was morally culpable and constitutes a willful or wanton negligence or recklessness. Accordingly, Plaintiffs are entitled to damages, including treble damages, punitive damages, injunctive relief, and attorneys' fees pursuant to New York GBL § 349.

**AS AND FOR A THIRD CAUSE OF ACTION
(NEW YORK ANTITRUST LAW: VIOLATION OF
SECTION 340 OF THE NEW YORK GENERAL BUSINESS)**

92. Plaintiffs repeat and reallege each and every allegation made in the preceding paragraphs of this Complaint, as though more fully set forth at length herein.

93. New York General Business Law § 340.1 provides:

Every contract, agreement, arrangement or combination whereby

A monopoly in the conduct of any business, trade or commerce or in the furnishing of any service in this state, is or may be established or maintained, or whereby

Competition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained or whereby

For the purpose of establishing or maintaining any such monopoly or unlawful interference with free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state any business, trade or commerce or furnishing of any service is or may be restrained, is hereby declared to be against public policy, illegal and void.

94. Thus, Section 340 of New York's General Business Law makes illegal and void any contract, arrangement, combination or agreement that restrains competition in any business, or

unlawfully interferes with the free exercise of any activity in the conduct of any business.

95. PBMs provide prescription drug management services to 95% of the patients covered by prescription drug benefit insurance in the United States. Defendants collectively control the vast majority of that market share. Defendants have joined together to use their market share to negatively control and eliminate the consumption of compound drugs in the PBM consumer market, or to effectively eliminate the market for compound drugs and to put independent compound pharmacies out of business.

96. Defendants' actions has an adverse effect on competition as a whole, by among other things, forcing physicians to prescribe inferior medicines for patients' particular conditions, or forcing them to forego participating in-network, by forcing patients to take inferior medicines or be denied the prescription drug benefit coverage to which they are entitled, and by forcing independent compound pharmacies out of business.

97. Because Defendants have joined together to effectively ban or boycott the purchase and production of compound medicines, Defendants have committed a *per se* violation of New York's antitrust laws.

98. Alternatively, as described above, Defendants actions have had an adverse effect on competition as a whole, by, among other things, forcing physicians to limit patient access to the treatment that they have determined best suits the patient's interest or being denied access to the insurance plans that provide coverage for prescription medications. Under the rule of reason, Defendants are liable, jointly and severally to Plaintiffs for the damages that Plaintiffs have suffered as a result of Defendants' actions, the amount of such damages to be determined at trial, plus attorneys' fees. Such damages are subject to trebling pursuant to General Business Law § 340.

**AS AND FOR A FOURTH CAUSE OF ACTION
(UNFAIR INSURANCE PRACTICES)**

99. Defendants have committed acts of boycott, coercion and intimidation to force physicians to cease prescribing compounded medicines or be investigated for fraud and abuse and potentially terminated from these PBM provider networks, which has resulted in an unreasonable restraint in the business of health insurance.

100. Defendants' actions are part of their general business practices. These general business practices have been performed or committed with respect to physicians and patients throughout the State of New York as well as with respect to physicians and patients in other states.

101. The acts of boycott, coercion and intimidation committed by Defendants stem from their agreement, understanding and/or arrangement among themselves to eliminate compound drugs from the prescription drug benefit market by effectively boycotting, coercing, and intimidating physicians, patients, and pharmacists who prescribe, take, and prepare compound medicine.

102. Defendants have imposed unreasonable restraints on trade by establishing arbitrary hurdles to prescribing and receiving compound medicines and by imposing impossible hurdles for independent compound pharmacies to process compound drug claims.

103. Through these acts, Defendants have committed violations of the statutes prohibiting unfair methods of competition and unfair and deceptive practices and acts in the business of insurance, including but not limited to, Insurance Law § 2401, *et seq.*, as a results of their unfair insurance practices.

**AS AND FOR A FIFTH CAUSE OF ACTION
(PERMANENT INJUNCTION)**

104. Plaintiffs repeat and allege the foregoing paragraphs set forth herein.

105. Plaintiffs have no adequate remedy at law.

106. Plaintiffs are entitled to a permanent injunction prohibiting Defendants from:

(a) Eliminating from insurance coverage those chemicals, drugs and other ingredients used by HM Compounding Services, LLC ("HMC") and other compounding pharmacies in the preparation of compounded medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by a defendant pursuant to a health insurance program and which had heretofore been covered by the patient's insurance;

(b) Refusing to process and pay claims for payment submitted by HMC for compounded medications prescribed by physicians for their patients who have prescription drug benefits administered by a defendant;

(c) Enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compounded medications prescribed by their physicians;

(d) Denying prescription drug benefit coverage to Victor Paduano, Frank Scala, and Nick

Canner and all other persons similarly situated who have prescriptions for compounded medications prescribed for them by their licensed physicians and who have prescription drug benefit coverage which is administered by a defendant; and; and enjoining Defendants

(e) To reinstate in full force and effect nunc pro tunc (i) the Provider Agreement dated August 15, 2013, entered into by and between HMC and ORx and ordering payment of all rejected compound medicine claims on those policies; (ii) the Provider Agreement dated December 17, 2012, entered into by and between HMC and CVSC and ordering payment of all rejected compound medicine claims on those policies; (iii) the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and Wholesale Alliance TPS, LLC d/b/a Third Party Station on

behalf of Third Party Payer ESI and ordering payment of all rejected compound medicine claims on those policies

WHEREFORE, Plaintiffs demand judgment as follows:

ON THE FIRST CAUSE OF ACTION an order enjoining Defendants from making false and/or misleading statements regarding the safety and efficacy of compounded medications; directing Defendants to send corrective notices to patients and physicians regarding the safety and efficacy of compounded medications; and processing and paying claims for the compounded medications prescribed by physicians for the patients to the same extent and the same manner as provided prior to the Defendants false and misleading statements, together with monetary damages in an amount to be determined.

ON THE SECOND CAUSE OF ACTION an order enjoining Defendants from making false and/or misleading statements regarding the safety and efficacy of compounded medications; directing Defendants to send corrective notices to patients and physicians regarding the safety and efficacy of compounded medications; and processing and paying claims for the compounded medications prescribed by physicians for the patients to the same extent and the same manner as provided prior to the Defendants false and misleading statements, together with monetary damages in an amount to be determined. Plaintiffs also seek an order against Defendants, permanently enjoining Defendants (a) from eliminating from insurance coverage those chemicals, drugs and other ingredients used by HM Compounding Services, LLC ("HMC") and other compounding pharmacies in the preparation of compounded medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by a defendant pursuant to a health insurance program and which had heretofore been covered by

the patient's insurance; (b) from refusing to process and pay claims for payment submitted by HMC for compounded medications prescribed by physicians for their patients who have prescription drug benefits administered by a defendant; (c) from enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compounded medications prescribed by their physicians; (d) from denying prescription drug benefit coverage to Victor Paduano, Frank Scala, Nick Canner and all other persons similarly situated who have prescriptions for compounded medications prescribed for them by their licensed physicians and who have prescription drug benefit coverage which is administered by a defendant; and (e) to reinstate in full force and effect nunc pro tunc (i) the Provider Agreement dated August 15, 2013, entered into by and between HMC and ORx and ordering payment of all rejected compound medicine claims on those policies; (ii) the Provider Agreement dated December 17, 2012, entered into by and between HMC and CVSC and ordering payment of all rejected compound medicine claims on those policies; (iii) the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and

Wholesale Alliance TPS, LLC d/b/a Third Party Station on behalf of Third Party Payer ESI and ordering payment of all rejected compound medicine claims on those policies, together with treble monetary damages in an amount to be determined at trial, punitive damages, and attorneys' fees.

ON THE THIRD CAUSE OF ACTION against Defendants, an order permanently enjoining Defendants (a) from eliminating from insurance coverage those chemicals, drugs and other ingredients used by HM Compounding Services, LLC ("HMC") and other compounding pharmacies in the preparation of compounded medications prescribed by licensed physicians for

their patients who have prescription drug benefit coverage administered by a defendant pursuant to a health insurance program and which had heretofore been covered by the patient's insurance; (b) from refusing to process and pay claims for payment submitted by HMC for compounded medications prescribed by physicians for their patients who have prescription drug benefits administered by a defendant; (c) from enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compounded medications prescribed by their physicians; (d) from denying prescription drug benefit coverage to Victor Paduano, Frank Scala, Nick Canner and all other persons similarly situated who have prescriptions for compounded medications prescribed for them by their licensed physicians and who have prescription drug benefit coverage which is administered by a defendant; and (e) to reinstate in full force and effect nunc pro tunc (i) the Provider Agreement dated August 15, 2013, entered into by and between HMC and ORx and ordering payment of all rejected compound medicine claims on those policies; (ii) the Provider Agreement dated December 17, 2012, entered into by and between HMC and CVSC and ordering payment of all rejected compound medicine claims on those policies; (iii) the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and Wholesale Alliance TPS, LLC d/b/a Third Party Station on behalf of Third Party Payer ESI and ordering payment of all rejected compound medicine claims on those policies, together with treble damages in an amount to be determined at trial, punitive damages, and attorneys' fees.

ON THE FOURTH CAUSE OF ACTION against Defendants, an order permanently enjoining Defendants (a) from eliminating from insurance coverage those chemicals, drugs and other ingredients used by HM Compounding Services, LLC ("HMC") and other compounding

pharmacies in the preparation of compounded medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by a defendant pursuant to a health insurance program and which had heretofore been covered by the patient's insurance; (b) from refusing to process and pay claims for payment submitted by HMC for compounded medications prescribed by physicians for their patients who have prescription drug benefits administered by a defendant; (c) from enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compounded medications prescribed by their physicians; (d) from denying prescription drug benefit coverage to Victor Paduano, Frank Scala, Nick Canner and all other persons similarly situated who have prescriptions for compounded medications prescribed for them by their licensed physicians and who have prescription drug benefit coverage which is administered by a defendant; and (e) to reinstate in full force and effect nunc pro tunc (i) the Provider Agreement dated August 15, 2013, entered into by and between HMC and ORx and ordering payment of all rejected compound medicine claims on those policies; (ii) the Provider Agreement dated December 17, 2012, entered into by and between HMC and CVSC and ordering payment of all rejected compound medicine claims on those policies; (iii) the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and Wholesale Alliance TPS, LLC d/b/a Third Party Station on behalf of Third Party Payer ESI and ordering payment of all rejected compound medicine claims on those policies.

ON THE FIFTH CAUSE OF ACTION against Defendants, an order permanently enjoining defendants (a) from eliminating from insurance coverage those chemicals, drugs and other ingredients used by HM Compounding Services, LLC ("HMC") and other compounding

pharmacies in the preparation of compounded medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by a defendant pursuant to a health insurance program and which had heretofore been covered by the patient's insurance; (b) from refusing to process and pay claims for payment submitted by HMC for compounded medications prescribed by physicians for their patients who have prescription drug benefits administered by a defendant; (c) from enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compounded medications prescribed by their physicians; (d) from denying prescription drug benefit coverage to Victor Paduano, Frank Scala, Nick Canner and all other persons similarly situated who have prescriptions for compounded medications prescribed for them by their licensed physicians and who have prescription drug benefit coverage which is administered by a defendant; and (e) to reinstate in full force and effect nunc pro tunc (i) the Provider Agreement dated August 15, 2013, entered into by and between HMC and ORx and ordering payment of all rejected compound medicine claims on those policies; (ii) the Provider Agreement dated December 17, 2012, entered into by and between HMC and CVSC and ordering payment of all rejected compound medicine claims on those policies; (iii) the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and Wholesale Alliance TPS, LLC d/b/a Third Party Station on behalf of Third Party Payer ESI and ordering payment of all rejected compound medicine claims on those policies.

All together with cost disbursements, expenses and reasonable attorneys' fees as against defendants and such other and further relief as the Court deems just, proper and equitable.

Dated: Garden City, New York
September 10, 2014

JASPAN SCHLESINGER LLP
Attorneys for Plaintiffs

By: _____

STEVEN R. SCHLESINGER
STANLEY A. CAMHI
SHANNON E. BOETTJER
300 Garden City Plaza
Garden City, New York 11530
516-746-8000

VERIFICATION

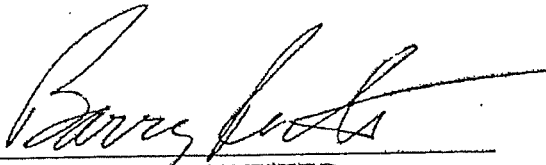
STATE OF NEW YORK

ss.:

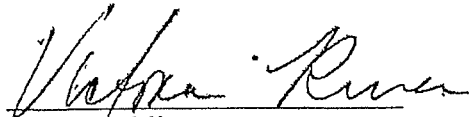
COUNTY OF BROOKLYN)

BARRY REITER, being duly sworn, deposes and says:

I am one of the Plaintiffs in this proceeding; I have read the foregoing VERIFIED COMPLAINT, know the contents thereof, and the same is true to my knowledge except as to those matters stated to be alleged upon information and belief, and as to those matters, I believe them to be true.


BARRY REITER

Sworn to before me this
10 day of September, 2014


Notary Public

VICTORIA RIVERA ABILIA
NOTARY PUBLIC-STATE OF NEW YORK
No. 01R16309625
Qualified in Kings County
My Commission Expires August 11, 2018

Index No.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NASSAU

VICTOR PADUANO, FRANK SCALA, NICK CANNER on
behalf of themselves and other similarly situated Individuals, and
HM COMPOUNDING SERVICES, LLC,

Plaintiff,

-against-

EXPRESS SCRIPTS, INC., CVS CAREMARK CORP.,
OPTUMRx, INC., AND PRIME THERAPEUTICS LLC,

Defendants.

SUMMONS AND VERIFIED COMPLAINT

JASPAN SCHLESINGER LLP

Attorneys for Plaintiffs
300 Garden City Plaza
Garden City, New York 11530-3324
(516) 746-8000

To:

Certified Pursuant to Rule 130-1.1-a

Attorney(s) for

Steven R. Schlesinger, Attorney

Service of a copy of the within

is hereby admitted.

Dated:

.....
Attorney(s) for

PLEASE TAKE NOTICE

Notice of
Entry

that the within is a (certified) true copy of a
entered in the office of the clerk of the within named Court on

200_

Notice of
Settlement

that an Order of which the within is a true copy will be presented for settlement to the Honorable
, one of the judges of the within named Court,

at
on 200_ at m.

Dated:

EXHIBIT 2

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NASSAU

----- X
VICTOR PADUANO, FRANK SCALA, NICK
CANNER on behalf of themselves and other
similarly situated Individuals, and HM
COMPOUNDING SERVICES, LLC,

Index No. 604739/2014

**NOTICE OF FILING NOTICE OF
REMOVAL**

Plaintiffs,

vs.

EXPRESS SCRIPTS, INC., CVS CAREMARK
CORP., OPTUMRx, INC., and PRIME
THERAPEUTICS, LLC,

Defendants.

----- X

TO: Stanley A. Camhi
Shannon E. Boettjer
JASPAN SCHLESINGER LLP
300 Garden City Plaza
Garden City, New York 11530

Attorneys for Plaintiffs
Served via ECF

PLEASE TAKE NOTICE that Defendants, CVS Caremark Corp. (now known as CVS Health Corporation), Express Scripts Inc., OptumRx, and Prime Therapeutics, LLC, by and through their undersigned counsel, have removed this case to the United States District Court for the Eastern District of New York. A copy of the Notice of Removal filed in the United States District Court is attached.

Dated: September 12, 2014

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*Attorneys for Defendant
Prime Therapeutics LLC*

EXHIBIT 3

UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF NEW YORK

VICTOR PADUANO, FRANK SCALA, NICK CANNER
on behalf of themselves and other similarly situated
individuals, and HM COMPOUNDING SERVICES, LLC,

Plaintiffs,

v.

EXPRESS SCRIPTS, INC., CVS CAREMARK CORP.,
OPTUMRx, INC., and PRIME THERAPEUTICS LLC,

Defendants.

Case No.

DECLARATION OF MICHAEL L. KLEIN

I, Michael L. Klein, hereby declare and state as follows:

1. I am a Director in the Fraud, Waste and Abuse Services group for Express Scripts Holding Company ("Express Scripts").
2. This declaration is based upon my review of records maintained by Express Scripts in the ordinary course of business and personal knowledge of the facts set forth herein.
3. I have reviewed Express Scripts records relating to prescription drug claims submitted by HM Compounding Services LLC (NABP 3198923 and 3360524) ("HM Compounding") to Express Scripts for reimbursement.
4. From January 1, 2014 to September 1, 2014, HM Compounding submitted \$19,151,546.70 in prescription drug claims to Express Scripts for reimbursement.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 12 day of September, 2014.


Michael Klein